ARMY MEDICINE
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Globally Harmonized System (GHS)

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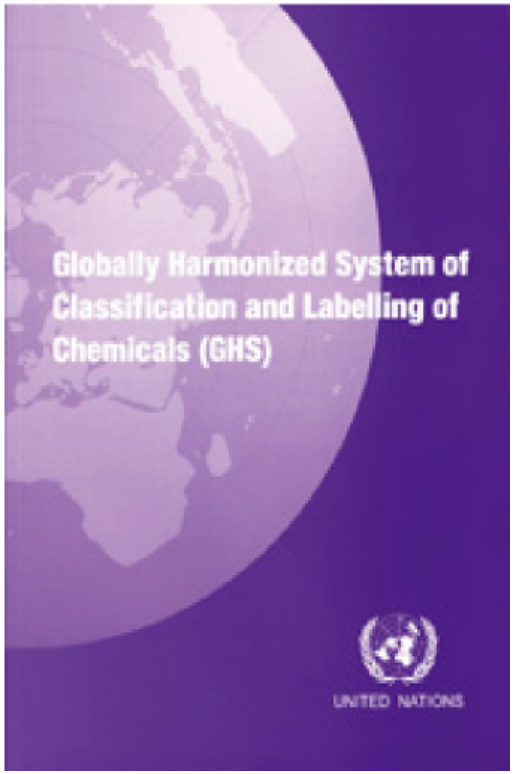
What is GHS?



The GHS is an acronym for *The Globally Harmonized System of Classification and Labeling of Chemicals*.

The GHS is a system for standardizing and harmonizing the classification and labeling of chemicals. It is a logical and comprehensive approach to:

- Defining health, physical and environmental hazards of chemicals;
- Creating classification processes that use available data on chemicals for comparison with the defined hazard criteria; and
- Communicating hazard information, as well as protective measures, on labels and Safety Data Sheets (SDS).

Why is the GHS needed?

- No country has the ability to identify and specifically regulate every hazardous chemical product.
- For example, in the United States, there are an estimated 650,000 such products.
- Adoption of requirements for information to accompany the product helps address protection needs.

Why? (cont.)

- Many different countries have come to the same conclusion about using information dissemination as a regulatory means to address chemical hazards.
- While similar, they are different enough to require multiple labels and safety data sheets for the same product in international trade.

Why? (cont.)

- Countries with systems have different requirements for hazard definitions as well as information to be included on a label or material safety data sheet.
- For example, a product may be considered flammable or toxic in one country, but not in another to which it is being shipped.

Why? (cont.)

- These differences impact both protection and trade.
- In the area of protection, users in countries that don’t have specific requirements may see different label warnings or data sheet information for the same chemical.

Why? (cont.)

- In the area of trade, the need to comply with multiple regulations regarding hazard classification and labelling is costly and time-consuming.
- Small to medium enterprises are effectively precluded from international trade in chemicals due to the regulatory burden of compliance.

Benefits of Harmonization

- Countries, international organizations, chemical producers and users of chemicals all benefit.
  - Enhance protection of humans and environment.
  - Facilitate international trade in chemicals.
  - Reduce need for testing and evaluation.
  - Assist countries and international organizations to ensure the sound management of chemicals.

International Mandate

- An international mandate to harmonize was adopted at the United Nations Conference on the Environment and Development (UNCED) in 1992 in Brazil:
  - *A globally-harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.*

Status in the US

- US agencies with requirements for labels and MSDSs have been actively involved in the development process.
- Could be adopted either:
  - Legislatively in Congress; or
  - By regulation in each affected agency.
- On October 25, OSHA took the last step to officially adopt the Globally Harmonized System of Classification and Labeling (GHS) into the U.S.'s Hazard Communication Standard. The Office of Management and Budget (OMB) now has 90 days to review and finalize the rule before it becomes official in the Federal Register.

Principles Of Harmonization

- Protections will not be reduced; comprehensibility will be key.
- All types of chemicals will be covered; will be based on intrinsic properties (hazards) of chemicals.
- All systems will have to be changed.

The Scope of the GHS

- Covers all hazardous chemical substances, dilute solutions, and mixtures.
- Pharmaceuticals, food additives, cosmetics and pesticide residues in food will not be covered at the point of intentional intake, but will be covered where workers may be exposed, and in transport.

Confidential Business Information

- Previously referred to as Trade Secrets
- National authorities should establish appropriate mechanisms for CBI protection. CBI will not be harmonized under the GHS.
- The provisions for CBI protection should not compromise the health and safety of users.
- CBI claims should be limited to the names of chemicals and their concentrations in mixtures.
- Mechanisms should be established for disclosure in emergency and non-emergency situations.

The GHS Elements

Classification Criteria

- Health and Environmental Hazards
- Physical Hazards
- Mixtures

Hazard Communication

- Labels
- Safety Data Sheets

Comprehensibility

Guiding principles:

- Information should be conveyed in more than one way.
- The comprehensibility of the components of the system should take account of existing studies and evidence gained from testing.
- The phrases used to indicate the degree (severity) of hazard should be consistent across different hazard types.

What are GHS Hazards?

GHS expands the types of hazards used in MSDS' currently. The categories of hazards are:

- Physical
- Health
- Environmental

What are GHS Physical Hazards?

Physical Hazards

- Explosives
- Flammable Gases
- Flammable Aerosols
- Oxidizing Gases
- Gases Under Pressure
- Flammable Liquids
- Flammable Solids
- Self-Reactive Substances
- Pyrophoric Liquids
- Pyrophoric Solids
- Self-Heating Substances
- Substances which, in contact with water, emit flammable gases
- Oxidizing Liquids
- Oxidizing Solids
- Organic Peroxides
- Corrosive to Metals

What are GHS Health Hazards?

Health Hazards

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicology
- Target Organ Systemic Toxicity – Single Exposure
- Target Organ Systemic Toxicity – Repeated Exposure
- Aspiration Toxicity

What are GHS Environmental Hazards?

Environmental Hazards

Hazardous to the Aquatic Environment **New**

- Acute aquatic toxicity
- Chronic aquatic toxicity
  - o Bioaccumulation potential
  - o Rapid degradability

Hazard Communications

1910.1200(e)

Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

- A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas);

- The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

Hazard Communications

- "Multi-employer workplaces." Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:

  - The methods the employer will use to provide the other employer(s) on-site access to material safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;

  - The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

  - The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

Hazard Communications

- The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

- The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.1020 (e).

- Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

Role of the SDS in the GHS

- The SDS should provide comprehensive information about a chemical substance or mixture.
- Primary Use: The Workplace
- Employers and workers use the SDS as a source of information about hazards and to obtain advice on safety precautions.

SDS Format: 16 headings

1. Identification
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure control/personal protection

SDS Format: 16 headings

9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
1.Product and company identification	- GHS product identifier - Other means of identification. - Recommended use of the chemical and restrictions on use. - Supplier's details (including name, address, phone number etc). - Emergency phone number.	- Product identity same as on label - Name address and telephone number of the manufacturer, distributor, employer or other responsible party
2. Hazards identification	- GHS classification of the substance/mixture and any regional information. - GHS label elements, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, e.g. flame, skull and crossbones.) - Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the GHS.	- health hazards including acute and chronic effects, listing target organs or systems - Signs & symptoms of exposure - conditions generally recognized as aggravated by exposure - primary routes of exposure - if listed as a carcinogen by OSHA, IARC, NTP - See Sections 5,9,10 for physical hazards

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
3. Composition/ information on ingredients	Substance- Chemical identity - Common name, synonyms etc. - CAS number, EC number, etc. - Impurities and stabilizing additives that are themselves classified and which contribute to the classification of the substance. Mixture - The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels. Note: For information on ingredients, the competent authority rules for CBI (Confidential Business Information) take priority over the rules for product identification	- Chemical and common name of ingredients contributing to known hazards - For untested mixtures, the chemical & common name of ingredients at 1% or more that present a health hazard and those that present a physical hazard in the mixture - Ingredients at 0.1% or greater, if listed carcinogens

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
4.First-aid measures	- Description of necessary measures, subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion. - Most important symptoms/effects, acute and delayed. - Indication of immediate medical attention and special treatment needed, if necessary	- emergency& first aid procedures
5. Fire-fighting measures	- Suitable (and unsuitable) extinguishing media. - Specific hazards arising from the chemical (e.g. nature of any hazardous combustion products). - Special protective equipment and precautions for fire-fighters	- flammable property information such as flash point - physical hazards - generally applicable control measures

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
6. Accidental release measures	- Personal precautions, protective equipment and emergency procedures. - Environmental precautions. - Methods and materials for containment and cleaning up.	- procedures for clean up of spills and leaks
7. Handling and storage	-Precautions for safe handling. - Conditions for safe storage, including any incompatibilities	- precautions for safe handling & use, including appropriate hygienic practices

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
8. Exposure controls/personal protection	- Control parameters e.g. occupational exposure limit values or biological limit values. - Appropriate engineering controls. - Individual protection measures, such as personal protective equipment	- General applicable control measures - appropriate engineering controls and work practices - protective measures during maintenance & repair - personal protective equipment - permissible exposure levels, threshold limit values, listed by OSHA, ACGIH, or established company limits.

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
9. Physical and chemical properties	- Appearance (physical state, color etc) - Odor - Odor threshold - pH - melting point/freezing point - initial boiling point and boiling range - flashpoint: - evaporation rate - flammability (solid, gas) - upper/lower flammability or explosive limits - vapor pressure - vapor density - relative density: - Solubility(ies) - partition coefficient: n-octanol/water: - auto-ignition temperature - decomposition temperature	- physical & chemical characteristics of hazardous chemicals such as vapor pressure & density.

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
10. Stability and reactivity	- Chemical stability. - Possibility of hazardous reactions. - Conditions to avoid (e.g. static discharge, shock or vibration) - Incompatible materials - Hazardous decomposition products	- organic peroxides, pyrophoric, unstable (reactive), or water-reactive hazards - physical hazards, including reactivity and hazardous polymerization
11. Toxicological information	- Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: - information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); - Symptoms related to the physical, chemical and toxicological characteristics; - Delayed and immediate effects and also chronic effects from short- and long-term exposure. - Numerical measures of toxicity (such as acute toxicity estimates)	- See also Section 2 - [health hazards including acute and chronic effects, listing target organs or systems - Signs& symptoms of exposure - primary routes of exposure - if listed as a carcinogen by OSHA, IARC, NTP]

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
12. Ecological information	- Ecotoxicity (aquatic and terrestrial, where available). - Persistence and degradability - Bioaccumulative potential - Mobility in soil - Other adverse effects	- No present requirements
13. Disposal considerations	- Description of waste residues and information on their safe handling and methods of disposal, including any contaminated packaging.	- See section 7 - No present requirements

MSDS Comparison by Section

GHS MSDS Sections	GHS SDS	OSHA HCS
14. Transport information	- UN number - UN Proper shipping name. - Transport Hazard class(es). - Packing group, if applicable. - Marine pollutant (Y/N). - Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.	- No present requirements
15. Regulatory information	- Safety, health and environmental regulations specific for the product in question.	- No present requirements
16. Other information	- Other information including information on preparation and revision of the SDS	- Date of preparation of MSDS or date of last change

Labeling

The standardized label elements included in the GHS are:

- **Symbols (hazard pictograms)**: Convey health, physical and environmental hazard information, assigned to a GHS hazard class and category.
- **Signal Words:** “Danger” or “Warning” are used to emphasize hazards and indicate the relative level of severity of the hazard, assigned to a GHS hazard class and category**.**
- **Hazard Statements:** Standard phrases assigned to a hazard class and category that describe the nature of the hazard.

Labeling

Signal Words

The signal word indicates the relative degree of severity a hazard. The signal words used in the GHS are:

"Danger" for the more severe hazards, and
"Warning" for the less severe hazards.

Signal words are standardized and assigned to the hazard categories within endpoints. Some lower level hazard categories do not use signal words. Only **one** signal word corresponding to the class of the most severe hazard should be used on a label.

Hazard Statements

Hazard statements are standardized and assigned phrases that describe the hazard(s) as determined by hazard classification. An appropriate statement for each GHS hazard should be included on the label for products possessing more than one hazard.

Labeling

Meets pre-GHS guidelines

ToxiFlam

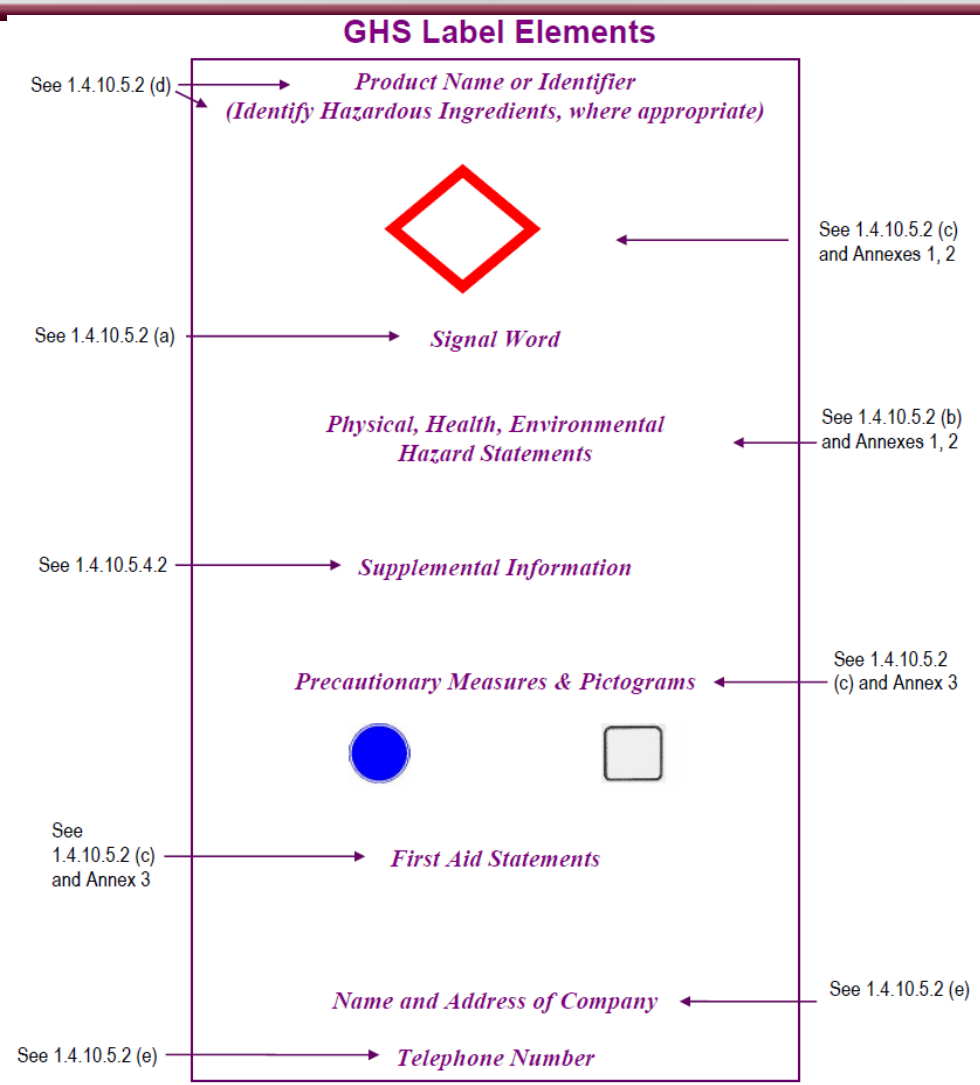
TOXIC
COMBUSTIBLE LIQUID AND VAPOR

Do not taste or swallow. Do not take internally. Wash thoroughly after handling. Keep away from heat, sparks and flame. Keep container closed. Use only with adequate ventilation.

FIRST AID
If swallowed, do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

See Material Safety Data Sheet for further details regarding safe use of this product.
My Company, My Street, MyTown NJ 00000, Tel: 444 999 9999

Labeling



The Section numbers refer to the sections in the GHS Document or "Purple Book".

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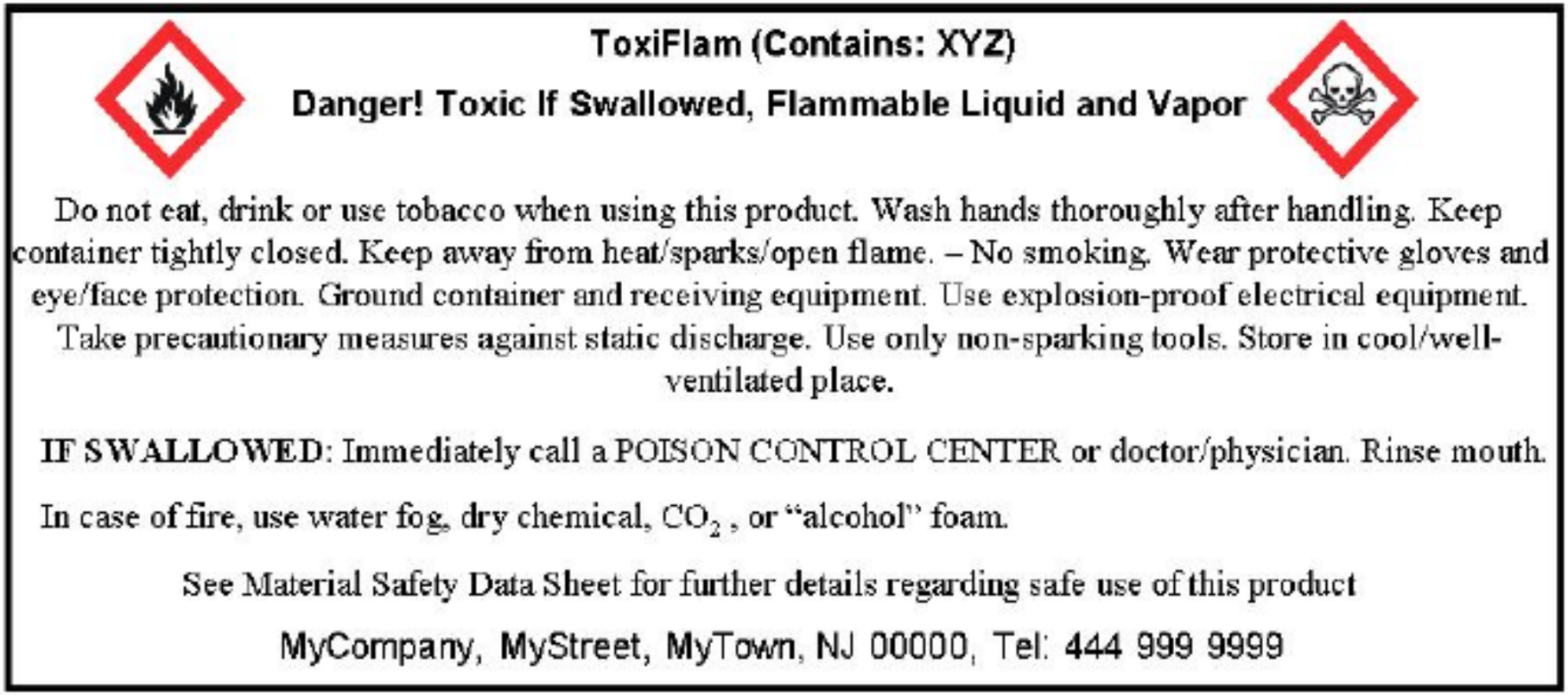
Labeling

GHS Label

Figure 4.12 Example GHS Inner Container Label (e.g., bottle inside a shipping box)



ToxiFlam (Contains: XYZ)

Danger! Toxic If Swallowed, Flammable Liquid and Vapor

Do not eat, drink or use tobacco when using this product. Wash hands thoroughly after handling. Keep container tightly closed. Keep away from heat/sparks/open flame. – No smoking. Wear protective gloves and eye/face protection. Ground container and receiving equipment. Use explosion-proof electrical equipment. Take precautionary measures against static discharge. Use only non-sparking tools. Store in cool/well-ventilated place.

IF SWALLOWED: Immediately call a POISON CONTROL CENTER or doctor/physician. Rinse mouth.

In case of fire, use water fog, dry chemical, CO_2 , or "alcohol" foam.

See Material Safety Data Sheet for further details regarding safe use of this product

MyCompany, MyStreet, MyTown, NJ 00000, Tel: 444 999 9999

Pictograms

GHS Pictograms and Hazard Classes		
• Oxidizers	• Flammables • Self Reactives • Pyrophorics • Self-Heating • Emits Flammable Gas • Organic Peroxides	• Explosives • Self Reactives • Organic Peroxides
• Acute toxicity (severe)	• Corrosives	• Gases Under Pressure
• Carcinogen • Respiratory Sensitizer • Reproductive Toxicity • Target Organ Toxicity • Mutagenicity • Aspiration Toxicity	• Environmental Toxicity	• Irritant • Dermal Sensitizer • Acute toxicity (harmful) • Narcotic Effects • Respiratory Tract Irritation

Acute Toxicity Pictogram

ACUTE ORAL TOXICITY – Annex 1					
	Category 1	Category 2	Category 3	Category 4	Category 5
LD_{50}	≤ 5 mg/kg	> 5 < 50 mg/kg	≥ 50 < 300 mg/kg	≥ 300 < 2000 mg/kg	≥ 2000 < 5000 mg/kg
Pictogram					No symbol
Signal word	Danger	Danger	Danger	Warning	Warning
Hazard statement	Fatal if swallowed	Fatal if swallowed	Toxic if swallowed	Harmful if swallowed	May be harmful if swallowed

Labeling

Is there a specific GHS label format / layout?

The GHS hazard pictograms, signal word and hazard statements should be located together on the label. The actual label format or layout is not specified in the GHS.

GHS Training

The GHS states in Chapter 1.4, Section1.4.9, the importance of training all target audiences to recognize and interpret label and/or SDS information, and to take appropriate action in response to chemical hazards.

Training requirements should be appropriate for and commensurate with the nature of the work or exposure. Key target audiences include workers, emergency responders and also those responsible for developing labels and SDSs.

GHS Training

As is in the current system, workers must be trained on the hazards they might encounter ***before*** they enter the workplace.

There is no grace period for this training.

Conclusion

- Development of the GHS has been a long and complicated process.
- Hopefully, it will be adopted by countries around the world and will achieve the projected benefits for protection and trade.

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